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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE THALOMID AND REVLIMID ANTITRUST LITIGATION	Civil Action No. 2:14-cv-6997-MCA-MAH Honorable Madeline Cox Arleo, U.S.D.J. (Document Filed Electronically)

CELGENE CORPORATION'S MEMORANDUM IN OPPOSITION TO CLASS PLAINTIFFS' RENEWED MOTION FOR CLASS CERTIFICATION

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INTRODUCTION

The Court denied Plaintiffs' motion to certify a class of End Payors for three reasons: (1) Plaintiffs failed to provide a common method for proving injury-in-fact due to the presence of uninjured brand loyal consumers; (2) Plaintiffs failed to provide a reliable mechanism for excluding flat co-pay consumers; and (3) Plaintiffs failed to demonstrate that certification of an injunction class was appropriate under Rule 23(b)(2). Nevertheless, the Court allowed Plaintiffs a second chance to cure these defects. Plaintiffs' renewed motion confirms that they still cannot establish injury-in-fact on a class-wide basis because they offer no method for identifying either brand loyalists or flat co-pay consumers without individual inquiry.

Recognizing that they cannot fix these fundamental issues, Plaintiffs now ask the Court to change its mind or, in the alternative, to sanction a variety of tweaks designed to minimize—but not fix—the problems. Because Plaintiffs cannot satisfy the high standard required for a motion to reconsider, and because Plaintiffs' purported remedies only worsen their predominance problems, Plaintiffs' motion should be denied.

First, Plaintiffs propose a new type of damages class consisting only of third party payors ("TPPs"), but excluding PBMs. After the briefing on Plaintiffs' first motion was completed, however, both of Plaintiffs' experts conceded [redacted] Further, because these classes still include uninjured TPPs—TPPs who only insure brand loyalists—Plaintiffs again lack a common method for proving injury-in-fact.

Second, Plaintiffs propose to modify their original damages classes by delaying the start date until only 2.5 percent of the putative consumer class members would continue to choose the

brand. Plaintiffs offer only rampant speculation as to when this arbitrary generic penetration goal would have occurred, and the resulting claim-splitting would defeat many of the purported benefits of class treatment. Plaintiffs also suggest *including* in these classes the admittedly uninjured and unidentifiable flat copay consumers to dodge the ascertainability concern. This suggestion compounds Plaintiffs' brand loyalty issue by adding another group of uninjured consumers to the putative classes, and highlights Plaintiffs' inability to establish class-wide antitrust injury. Alternatively, Plaintiffs submit—without any new case law or analysis, and despite this Court's unambiguous ruling to the contrary—that identification of class members can wait until trial. For all the reasons the Court already explained, it cannot. Finally, Plaintiffs proffer a novel theory that brand loyalists—who *by definition* would not have chosen a generic—are nevertheless injured by a reduction in consumer choice sufficient to certify a Rule 23(b)(3) damages class. No court has ever sanctioned such a claim, which flouts fundamental concepts of antitrust injury.

Plaintiffs' efforts to certify an injunction class are similarly unavailing, as they have offered the Court no guidance on what specific relief they seek and cannot show that such a class would be cohesive.

ARGUMENT

Plaintiffs still fail to meet multiple critical requirements for certifying a class under Rule 23. Specifically, Plaintiffs' renewed motion should be denied because (a) they have failed to satisfy Rule 23(b)(3)'s predominance requirement with respect to the various damages classes now proposed, and (b) they have not met requirements for certifying an injunctive relief class pursuant to Rule 23(b)(2).

I. PLAINTIFFS' PROPOSED THIRD PARTY PAYOR ONLY DAMAGES CLASSES ARE NOT CERTIFIABLE BECAUSE INDIVIDUAL ISSUES PREDOMINATE.

In denying Plaintiffs' motion to certify their proposed damages classes, the Court gave Plaintiffs a second chance to cure the dispositive problems. Plaintiffs' response was not to address the issues raised by the Court. Rather, Plaintiffs argue that, at the very least, certification of classes comprised only of TPPs is appropriate. Plaintiffs are mistaken. For two separate reasons, TPP-only classes cannot be certified on the undisputed record developed in this case.

The first stems from Plaintiffs' last-minute exclusion of PBMs from their putative classes. During the prior class certification briefing, Plaintiffs belatedly argued that it was feasible to exclude PBMs because they did not actually pay for any part of the retail pharmacy purchase price of Thalomid or Revlimid. Therefore, Plaintiffs argued, because PBMs purportedly did not actually pay for the drugs, Plaintiffs did not have to account for any reimbursements involving PBMs; they simply could focus on prices paid only by TPPs and consumers. Testimony and analyses provided by Plaintiffs' experts *after* briefing on Plaintiffs' first certification motion was complete confirms that [redacted] Notwithstanding this now undisputed fact, Plaintiffs' TPP-only damages model fails to exclude those instances where PBMs paid for at least part of the cost of Thalomid and Revlimid. TPP-only classes that purportedly exclude PBMs therefore cannot be certified because Plaintiffs' damages expert has not articulated any class-wide methodology for estimating and excluding PBM damages from the case.

The second problem with Plaintiffs' proposed TPP-only classes relates to the same brand loyalty issue that the Court found dispositive with respect to consumers: If a TPP insures only a handful of consumers taking Thalomid or Revlimid, and those consumers are uninjured because

they would not have taken generic versions of the medications, the TPP also is uninjured. Because Plaintiffs still do not have a common method for identifying brand loyalists, let alone the TPPs that insure them, Plaintiffs cannot carry their burden of proving class-wide injury.

A. Plaintiffs' Damages Model Fails To Exclude Payments by PBMs.

Uncontroverted record evidence, provided after briefing on Plaintiffs' prior motion was complete, shows that [redacted] Plaintiffs' exclusion of PBMs in their proposed TPP classes therefore "create[s] issues . . . with the classwide damages model" that preclude certification. Opinion, Dkt. 250 (hereinafter "Op.") at 49.

1. The Court Previously Agreed that Excluding PBMs from the Classes Would Undermine Plaintiffs' Damages Model if PBMs Bore a Part of the Cost.

It is undisputed that Thalomid and Revlimid claims purportedly "paid" by a TPP are in fact usually paid to the pharmacy by the PBM, which then seeks reimbursement from the TPP for some or all of the purchase price. If the PBM pays more to the pharmacy than it receives in reimbursement from the TPP, it unquestionably bears a portion of the cost from an economic perspective. Dkt. 182 at 22; *see also id.*, [redacted] Celgene's original opposition to class certification argued that Plaintiffs could not satisfy their ascertainability burden because they offered no methodology for identifying which PBMs paid some of the price (and were therefore in the class) and which did not. Dkt. 182 at 22-26.

In their reply, Plaintiffs submitted a declaration from Mr. W. Paul DeBree, who concluded—without any analysis of the Thalomid and Revlimid payments at issue in this case—

that PBMs generally do not pay for prescriptions. Dkt. 210-4 ¶ 6.[1] Plaintiffs also offered to exclude PBMs from the class entirely—a tactic that Celgene preemptively explained may cure the ascertainability problems but would create equally dispositive predominance concerns.

The Court accepted Mr. DeBree's representation and allowed Plaintiffs to exclude PBMs, but acknowledged that *if* PBMs in fact paid for the drugs, Celgene's predominance concerns would be valid. *See* Op. at 49 ("[E]xcluding PBMs . . . would create issues with plaintiffs' impact and damages model because the model would incorporate damages suffered by TPPs who are ostensibly excluded from the class and . . . such a model could be problematic because it would not measure those damages attributable *only* to End Payors' theory" (quoting *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 575 (E.D. Tenn. 2014) (internal quotation marks and citations omitted)). The Court concluded: "Thus, *if the Court finds that PBMs potentially bear part or all of the cost of Thalomid and Revlimid*, it would create issues . . . if PBMs are excluded, with [Plaintiffs'] classwide damages model." Op. at 49 (emphasis added).[2]

[1] Plaintiffs offered Mr. DeBree's declaration in their original class certification *reply* brief, rather than in their opening motion. Celgene sought to depose him on that declaration and to offer a rebuttal to it, but the Court denied leave for surrebuttal, so no deposition was taken. *See* Dkts. 212, 219. Plaintiffs have now again moved for class certification but did not cite to or include Mr. DeBree's declaration. And Plaintiffs initially refused to make Mr. DeBree available for deposition, arguing that they were not relying upon his declaration in the present motion. When Celgene offered to withdraw its request for deposition if Plaintiffs would agree that they would not cite to, or otherwise rely on, Mr. DeBree in their reply brief on this renewed motion, Plaintiffs agreed to produce him for deposition.

[2] The Court also confirmed that, if PBMs do bear price risk, *including* them would create ascertainability problems. Op. at 49-50. Those problems—highlighted by Celgene in its first opposition—are not repeated here because Plaintiffs have now attempted to exclude PBMs.

2. Newly Provided Evidence Confirms that [redacted]

At that time, while the Court "d[id] not disagree" that payments by PBMs were "theoretically possible," it opined that such payments were not yet "borne out by any evidence in the record." Op. at 50 n.5; *see also id.* at 49 (explaining that predominance problems created by excluding PBMs were not "relevant here, as the Court is not convinced that PBMs potentially bear any or part of the cost of Thalomid and Revlimid").

Much has changed since then. In an expert report served after the close of briefing on Plaintiffs' first certification motion, Plaintiffs' damages expert, Dr. Leitzinger, conceded that [redacted]

Specifically, Dr. Leitzinger compared [redacted]

[3] Citations to "Ex." refer to the exhibits attached to the Declaration of John E. Schmidtlein, filed herewith. Citations to "Mot." refer to Plaintiffs' supplemental memorandum in support of their motion for class certification. Dkt. 264.

[4] [redacted]

[redacted]

Dr. Leitzinger's case-specific example also undermines Mr. DeBree's generalized assertion that [redacted] As Mr. DeBree acknowledged in deposition, [redacted]

3. Plaintiffs' Failure To Remove PBMs from Their Damages Model Precludes Certification.

At the class certification stage, Plaintiffs "must show that a reliable method is available to prove damages on a class-wide basis." Op. at 30 (quoting *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 171, 202 (E.D. Pa. 2015)); *see also Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) ("a model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to" theory "accepted for class-action treatment"). Despite Dr. Leitzinger's and Mr. DeBree's recent admissions, Plaintiffs have done nothing to cure the

predominance concerns that the Court warned would be present if Plaintiffs excluded PBMs (as they now do). *See* Op. at 49. Plaintiffs have not removed such payments from their damages model, nor could they without individualized analysis.

Dr. Leitzinger asserted in his merits report (served after the close of briefing on the prior motion for class certification) that [redacted] But this assertion is based only [redacted] Plaintiffs have done no additional analysis and conducted no additional discovery to determine [redacted].[5] Ex. 4 (Leitzinger 11/30/18 Dep.) at 44:3-44:10, 49:15-50:23; Ex. 3 (DeBree Dep.) at 124:24-125:7. What is more, Dr. Leitzinger's estimate did not include [redacted] Dr. Leitzinger's assertion [redacted] is therefore unacceptably speculative. *See Comcast*, 569 U.S. at 35 (confirming that courts must review an expert's methodology to determine if it is "a just and reasonable inference or speculative").

Whatever the actual amount, the resulting inflation of Plaintiffs' model represents a

[5] The reason Plaintiffs did not conduct further analysis of all PBMs on this issue presumably was because it was impractical to do so given the highly individualized nature of the inquiry, which itself would preclude certification. *See Comcast*, 569 U.S. at 34 (predominance requirement not met where "[q]uestions of individual damage calculations will inevitably overwhelm questions common to the class").

fundamental misalignment of Plaintiffs' theory of liability and their proposed damages. Under *Comcast* and its progeny, this precludes certification. *Id*. at 37 (recognizing that class-wide damages model is invalid if it "identifies damages that are not the result of the wrong"); *Franco v. Conn. Gen. Life Ins. Co*., 299 F.R.D. 417, 430 (D.N.J. 2014) (Chesler, J.) (court must ensure that "proffered model measures only those damages attributable to the plaintiff's theory of liability"), *aff'd*, 647 F. App'x 76 (3d Cir. 2016).

B. Plaintiffs Cannot Identify Uninjured TPPs Whose Customers Are Brand Loyalists.

The Court previously concluded that the presence of brand loyalists who would not have switched to a generic defeats predominance for Plaintiffs' proposed End Payor classes. The same problem defeats Plaintiffs' proposed TPP-only classes. [redacted] *See infra* Part II.A (explaining why presence of uninjured brand loyal class members defeats predominance).

Because Plaintiffs have no class-wide method for determining which TPPs were injured and which were not, the brand loyalty issue dooms the TPP classes, just as it dooms the End Payor classes. It is no answer that the number of affected TPPs may (theoretically) be fewer than the End Payor brand loyalists. In all events, Plaintiffs' TPP classes will require individualized

consumer testimony (including the very same affidavits Plaintiffs admit are necessary to identify brand loyalists) to prove injury-in-fact. Therefore, because Plaintiffs have not "provided any basis from which [the Court] could conclude that the number of affidavits to which [Celgene] will be able to mount a genuine challenge is so small that it will be administratively feasible to require those challenged affiants to testify at trial," certification should be denied. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53 (1st Cir. 2018).[6]

II. PLAINTIFFS FAIL TO MEET RULE 23(b)(3)'S PREDOMINANCE REQUIREMENT.

Alternatively, Plaintiffs again seek certification of broader End Payor classes consisting of both consumers and TPPs. In its October 30 opinion, the Court held that such classes could not be certified because Plaintiffs had not satisfied Rule 23(b)(3)'s predominance requirement. Op. at 29. Specifically, the Court explained that brand loyalists were uninjured and Plaintiffs had offered no method for identifying them without resorting to extensive individual inquiries. *Id*. at 23-26. Nonetheless, the Court allowed "Plaintiffs another opportunity to address this issue and to propose a method of identifying potential brand loyalists without resorting to individualized inquiry." *Id.* at 29. Plaintiffs have not cured those deficiencies; indeed, they have compounded the problem by adding another group of uninjured class members who cannot be identified with common proof—consumers with flat copays—to the putative classes.

Plaintiffs also suggest artificially moving the putative class start date back only for consumers by two-and-a-half years, until they allegedly reach a generic penetration rate of 97.5 percent. That unprecedented "fix" is grounded on a speculative and flawed theory that is undermined by Plaintiffs' expert's own analysis of [redacted]

[6] Plaintiffs noted that a petition for rehearing *en banc* was filed in *Asacol*. Mot. at 15 n.26. The First Circuit has since denied that petition. *See Asacol*, No. 18-1065 (ordered Jan. 23, 2019).

[redacted] And it would remove many of the efficiencies that may be gained by class treatment.

Because these broader End Payor classes would suffer from the same flaws identified in Part I, and because Plaintiffs still have failed to offer any class-wide methodology for proving injury-in-fact, the Court should again deny Plaintiffs' motion on predominance grounds.

A. Plaintiffs Cannot Establish Injury-in-Fact on a Class-Wide Basis Without Identifying Brand Loyalists with Common Proof.

Rule 23(b)(3)'s "predominance" component examines "whether the elements of the claims of the class can be proven at trial with 'common, as opposed to individualized, evidence.'" Op. at 20 (quoting *Taha v. Cty of Bucks*, 862 F.3d 292, 308 (3d Cir. 2017)). "To certify a class, 'the putative class must first demonstrate economic loss—that is, the fact of damage—on a common basis.'" Op. at 22 (quoting *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305-06 (3d Cir. 2016)). In order to meet this requirement, the Court directed Plaintiffs to "propose a method of identifying potential brand loyalists without resorting to individualized inquiry." Op. at 29. Plaintiffs' motion does not even attempt to do so. That should end the inquiry: Plaintiffs have failed to address the core issue underlying the Court's denial of class certification and have provided the Court no record to reverse its prior ruling.

Instead of addressing the Court's directive, Plaintiffs in effect request reconsideration, suggesting for the first time that "distribution logistics" problems, rather than brand loyalty, explain why ten percent of the class would not convert to a generic product had it been available. Mot. at 13-14. The sole basis for this argument is a wholly speculative and unsound analysis now offered by Dr. Leitzinger. *Id.* As explained below, this analysis does not provide any basis for predicting how many brand loyalists will continue taking the branded versions of Thalomid and Revlimid when a generic product comes to market.

First, Dr. Leitzinger acknowledges that [redacted]

[redacted] In short, although the prevalence of brand loyalists has repeatedly led courts to deny class certification,[7] [redacted] These concessions are sufficient reason to deny Plaintiffs' motion.

Second, the "analysis" that Dr. Leitzinger performed does not undermine the Court's prior finding regarding brand loyalists. Dr. Leitzinger [redacted] He observed that [redacted] This analysis is fundamentally flawed for many reasons.

For example, [redacted]

[7] *See, e.g.*, *Asacol*, 907 F.3d at 59-60; *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *12 (E.D. Pa. June 10, 2015).

[redacted]

[redacted]

[redacted] Given all of these

8 [redacted]

limitations and qualifications, one cannot say that [redacted]

Plaintiffs' theory also defies common-sense. [redacted]

B. Plaintiffs Have Compounded Their Predominance Problems by Including Flat Copay Consumers in the Putative Classes.

Not only have Plaintiffs failed to cure their brand loyalist problem, Plaintiffs' renewed motion in fact increases the prevalence of individual issues by including flat copay consumers whom Plaintiffs previously excluded precisely because they were not injured.

There is no dispute that flat copay consumers are not injured because they would have paid the same amount for their prescriptions regardless of whether it was for a brand or a generic medication. *See* Mot. at 10 (admitting flat copayers "did not suffer damages" and "would not have paid less in the but-for world"). Plaintiffs therefore excluded such consumers from their original class definitions. *See* Dkt. 150 at 1 n.1. In opposition, Celgene explained that Plaintiffs had failed to satisfy their ascertainability burden because Plaintiffs' proposed method of identifying flat copay consumers required extensive individualized inquiry. Dkt. 182 at 19-21.

The Court agreed and denied certification on ascertainability grounds. Op. at 44. But the Court gave Plaintiffs another opportunity "to demonstrate that the excluded, flat copay members of the class can be identified" with common proof. Op. at 46. Plaintiffs have not done so. Instead, their "solution" is to *include* those consumers in their latest putative classes. To whatever extent this technically solves the ascertainability problem, it creates an equally dispositive predominance problem.

Plaintiffs' revised damages classes now have not one, but two, significant groups of undeniably uninjured consumers that Plaintiffs cannot identify without individualized inquiries. This defeats predominance under Third Circuit precedent, as well as this Court's prior ruling. *See* Op. at 24-26; *Vista Healthplan*, 2015 WL 3623005, at *19 ("[W]hen every class member has the potential to be a brand loyalist [or] a person with a flat copay . . . , and the only way to identify persons who fall within those groups is individualized inquiry, individualized inquiries would predominate.").[9] As the *Asacol* Court explained: "[T]his is not a case in which a very small absolute number of class members might be picked off in a manageable, individualized process at or before trial." 907 F.3d at 53; *see also* [redacted]

This Court concluded as much when Plaintiffs' classes *only* included uninjured brand loyalists, Op. at 24-26, and Plaintiffs provide no basis for the Court to reconsider this decision, *see infra* Part II.F (describing high standard required for reconsideration motions). Plaintiffs'

[9] *Accord Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 190 (3d Cir. 2001) ("ascertaining which class members have sustained injury means individual issues predominate over common ones"); *Harnish*, 833 F.3d at 313 ("the inability to resolve [the fact of damages] in class-wide fashion will cause individual questions to predominate").

admission that [redacted]—is therefore certainly "beyond the outer limits of what can be considered *de minimis* for purposes of establishing predominance." *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 292 F. Supp. 3d 14, 138 (D.D.C. 2017) (evaluating class where 12.7 percent of class members uninjured); *see also Asacol*, 907 F.3d at 51-52 (overruling district court decision certifying class where 10 percent of consumers uninjured).[11]

C. Plaintiffs' New Arbitrary Start Date Does Not Solve the Predominance Problem.

Desperate to save their putative classes, Plaintiffs try to limit the number of uninjured class members to what they contend is an "indisputably *de minimis*" number by manipulating the start date of the class period, and thereby "excluding consumers from the class until generic penetration reaches, say, 97.5%" or "a smaller percentage if [the Court] so chooses." Mot. at 22 & n.34. This "highly artificial limitation[]" should be rejected, as it would "deprive the class[ ]action device of much of its utility." *Wenig v. Messerli & Kramer P.A.*, 2013 WL 1176062, at *6 (D. Minn. Mar. 21, 2013).

To certify a class under Rule 23(b)(3), the Court must find that "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ.

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[10] As Celgene's expert explains, Plaintiffs' estimates suffer from myriad issues and, as such, the number of uninjured flat copay consumers [redacted]

[11] [redacted] As the *Asacol* court recognized, condoning such evidence "would . . . put us on a slippery slope, at risk of an escalating disregard of the difference between representative civil litigation and statistical observations of tendencies and distributions." 907 F.3d at 55-56.

P. 23(b)(3). If the class period is limited as Plaintiffs suggest, consumers who filled prescriptions before Plaintiffs' new start dates—or, more troublingly, filled prescriptions both before and after those dates—would be forced to bring separate lawsuits to obtain full recovery. "Plainly, a class action that resolves only a fraction of the possible claims—based on the fortuity of the [purchase date]—is neither a 'fair' nor 'efficient' way to 'adjudicate the controversy.'" *Wenig*, 2013 WL 1176062, at *6; *see also Ebert v. Gen. Mills, Inc.*, 823 F.3d 472, 481 (8th Cir. 2016) (reversing grant of certification when definition was "artificially narrowed by the district court to achieve class status" because such narrowing "does not advance the efficiencies necessary for such [class] treatment").

Even assuming, *arguendo*, there is some magic to 97.5 percent generic penetration, Plaintiffs cannot reliably say when it would be reached—and they surely cannot do so in advance of trial. As discussed above, Dr. Leitzinger's analysis provides no reliable basis for estimating when (if ever) generic penetration for Thalomid or Revlimid will reach 97.5 percent of all prescriptions. *See supra* Part II.A; *see also In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 302 F.R.D. 448, 462-63 (N.D. Ohio 2014) (declining to impose end date "not connected to any relevant event" in favor of evidence-based dates). In short, Plaintiffs cannot satisfy the Court's predominance concerns without resort to unacceptably speculative tailoring of the class definition, which would eliminate many of the efficiencies of the class.

D. Identifying Uninjured Class Members Cannot Wait Until After Trial.

Alternatively, Plaintiffs suggest—just as they did previously—that they need not identify uninjured consumers at the class certification stage. *Compare* Mot. at 16-22, *with* Dkt. 210 at 12 *and* Dkt. 248. The Court soundly rejected this approach:

> Plaintiffs argue that identification of individual brand loyalists is a question of damages allocation that is inappropriate for class certification. Plaintiffs cite to out-of-circuit cases for the

> proposition that consumers can, at the damages stage, establish their injury through testimony that, given the choice, he or she would have purchased the generic. None of the cases cited by Plaintiffs applied Third Circuit standards for class certification . . . . [I]n *Vista*, the court specifically rejected the standards outlined [in those cases], explaining that the Third Circuit imposes greater standards of proof at the time of class certification. . . . This Court . . . is required to apply the greater standards of proof discussed in *Vista Healthplan* and, consequently, Plaintiffs' inability to identify a non-individualized means of identifying brand loyalists weighs against certification.

Op. at 24 (alterations, citations, and internal quotation marks omitted); *see also Asacol*, 907 F.3d at 52. Plaintiffs provide the Court no new law or evidence that could meet the high standard required for reconsideration. *See infra* Part II.F.

If anything, Plaintiffs' efforts to relitigate this issue merely underscore the difficulty with identifying brand loyalists at the class certification stage (which this Court rightly concluded is required in the Third Circuit). Plaintiffs' first suggestion is that the Court simply wish the difficulty away and award damages to all consumers under a "presumption" that everybody would purchase a generic if given the choice. Mot. at 18. Plaintiffs' suggestion is disingenuous at best, since there is no dispute that at least *some* consumers *would not* purchase a generic—Plaintiffs just do not know who. *See, e.g.*, [redacted] Mot. at 13 (acknowledging that "true 'brand loyalists' may exist").

Plaintiffs' second proposal—that the Court use consumer testimony in the form of an affidavit or declaration—is no better. Mot. at 19 (citing *City Select Auto Sales, Inc. v. BMW Bank of N. Am., Inc.*, 867 F.3d 434, 442 (3d Cir. 2017)). As Plaintiffs acknowledge, such an affidavit cannot be as simple as the inquiry in *City Select* (i.e., whether a consumer received the fax in question). 867 F.3d at 441-42. The proposed affidavit in this case would ask at least four questions regarding each consumer's habits with respect to other drugs, and it may further be

necessary for each consumer "to submit evidence that they had taken generic drugs when available in the past." Mot. at 19-20 & n.31. As the *Asacol* Court explained, because these affidavits are not admissible, *each consumer* would also need to be available to testify at trial so that Celgene may properly raise challenges to their injury claims. 907 F.3d at 53. Such a fact-specific and burdensome inquiry would unquestionably cause individual issues to predominate.

E. "Lack of Consumer Choice" Is Insufficient To Demonstrate the Class-Wide Antitrust Injury Required for a Rule 23(b)(3) Damages Class.

With no reliable, class-wide method to identify which putative class members suffered injury by paying more for Thalomid and Revlimid in the actual world than they would have paid in the but-for world, Plaintiffs proffer a different alleged injury never before recognized as a basis for certifying a damages class under Rule 23: lack of consumer choice. Mot. at 8-9. The Court should reject this erroneous argument.

As a preliminary matter, [redacted] Plaintiffs' novel theory also demonstrates a fundamental misunderstanding of antitrust law. Specifically, Plaintiffs conflate the concept of an antitrust *violation* committed by a defendant with antitrust *injury* suffered by a plaintiff. While a reduction of consumer choice has been recognized as an anticompetitive effect of an antitrust violation, it has never been accepted as an antitrust injury that would alone justify a class action for damages. Plaintiffs' suggestion to the contrary—i.e., that "[t]he Supreme Court has recognized that *antitrust injury* arises from denial of consumer choice," Mot. at 8 (emphasis added)—is simply incorrect. The cases Plaintiffs cite stand only for the unremarkable proposition that limiting or enhancing consumer choice can have anticompetitive or procompetitive effects, which makes the conduct more or less likely to constitute an antitrust violation. None of these opinions addressed

the requirement of antitrust injury or damage,[12] let alone Rule 23(b)(3)'s further requirement that such injury be susceptible to class-wide proof in a case involving brand loyal class members.

The same is true of Plaintiffs' cited Third Circuit authority. In *Deborah Heart and Lung Center v. Penn Presbyterian Medical Center*, for example, the Court separately evaluated the requirements of anticompetitive effects and antitrust injury. 2011 WL 6935276, at *5 (D.N.J. Dec. 30, 2011) (Bumb, J.). Tellingly, when discussing the anticompetitive effects of the alleged violation, the court noted the "loss of consumer choice." *Id*. at *7. But when discussing antitrust injury, the court focused only on the plaintiff's "lost revenues," *not* on any reduction in choice. *Id*. at *9.[13]

Plaintiffs' reliance on *Laumann v. National Hockey League* is similarly misplaced. 105 F. Supp. 3d 384 (S.D.N.Y. 2015). The *Laumann* Court's discussion of consumer choice was limited only to the plaintiffs' request to certify an *injunction* class under Rule 23(b)(2). *Id*. at 398-99; *see also id*. at 408 (discussing how "injunctive classes are fundamentally different than damages classes"). Indeed, in a companion opinion, the *Laumann* Court denied certification of the corresponding Rule 23(b)(3) damages class because plaintiffs could not "prove, through

[12] The Supreme Court explicitly noted that it was not addressing the injury requirement in two of the cases Plaintiffs cite. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla*., 468 U.S. 85, 97 n.14 (1984) ("[P]etitioner [previously] argued that respondents had suffered no injury . . . . Petitioner does not seek review on that question in this Court."); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp*., 472 U.S. 585, 607 (1985) ("The adverse impact of Ski Co.'s pattern of conduct on Highlands is not disputed in this Court."). And the third was brought by a government regulator (which need not show antitrust injury). *F.T.C. v. Ind. Fed'n of Dentists*, 476 U.S. 447, 447 (1986).

[13] *See also Tunis Bros. Co. v. Ford Motor Co*., 952 F.2d 715, 722, 727-28 (3d Cir. 1991) (discussing consumer choice as a potential anticompetitive effect under Rule of Reason analysis and not addressing injury requirement); *United States v. Brown Univ*., 5 F.3d 658, 672-75 (3d Cir. 1993) (discussing consumer choice as a potential anticompetitive effect under Rule of Reason analysis); *United States v. Dentsply Int'l, Inc*., 399 F.3d 181, 194 (3d Cir. 2005) (same).

common evidence, that all class members were injured by the alleged conspiracy." *Id*. at 398 (alterations and internal quotation marks omitted). In other words, the *Laumann* plaintiffs' consumer choice theory of antitrust injury provided no basis to certify a damages class.

F. Plaintiffs Cannot Satisfy the High Standard Required for a Motion To Reconsider.

As discussed above, Plaintiffs' renewed motion does not seriously try to cure the flaws the Court identified in denying their prior motion, but rather attacks the Court's reasoning. Mot. at 14-16. Though Plaintiffs do not say so, they are really moving for reconsideration.

"The standard of review involved in a motion for reconsideration is high and relief is to be granted sparingly." *Gaines v. Busnardo*, 2015 WL 5771233, at *3 (D.N.J. Sept. 30, 2015) (Simandle, J.). Alterations to a prior judgment are warranted only if the party seeking reconsideration "shows at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). None of those grounds is present here. Plaintiffs identify no new law or evidence and no clear errors in the Court's prior opinion. Plaintiffs' latest motion cites the same case law that they cited previously, which the Court already addressed. *Compare* Mot. at 14-16, 19, 21 (citing *Tyson*, *Neale*, *Kohen*, *Castro*, *City Select*, *Haliburton*, and *Bogosian*), *with* Dkt. No. 248, at 2-3 (same). Plaintiffs' request also is untimely, as it was not filed within 14 days. *See* N.J. Local Rule 7.1(i).

Plaintiffs' efforts to undercut the *Asacol* Court's holding by aligning themselves with the Supreme Court's decision in *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016), are particularly unavailing. Mot. at 15-16. In *Tyson Foods*, the Supreme Court evaluated

certification of a class of workers who did not receive statutorily mandated overtime pay for time spent donning and doffing protective gear. *Id*. at 1042. "Since the employees' claims relate[d] only to overtime, each employee had to show he or she worked more than 40 hours a week, inclusive of time spent donning and doffing, in order to recover." *Id*. at 1043. Tyson Foods failed to keep records of the donning and doffing time. *Id*. The plaintiffs therefore relied on "representative evidence" such as employee testimony, video recordings of donning and doffing at the plant, and an expert who identified average time estimates, through which the plaintiffs *were able to reliably identify* the uninjured employees (i.e., those who did not meet the 40-hour threshold and thus could not recover). *Id*. at 1043-44. In other words, the plaintiffs were able to demonstrate the fact of injury on a class-wide basis without resorting to individualized inquiries, thereby satisfying their predominance burden.

That is not the case here. Plaintiffs' statistical evidence does not identify which individual putative class members suffered injury-in-fact and which did not, nor can it reliably predict how many brand loyalists are in the putative class. As the Court recognized in its prior opinion, two untenable options are therefore present: If Plaintiffs use average generic penetration rates to show class-wide injury, Celgene is denied "the opportunity to press at trial genuine challenges to allegations of injury-in-fact;" on the other hand, if Plaintiffs use consumer testimony from every class member on their brand preferences, "individual inquiries regarding this issue would overwhelm common issues at trial." Op. at 26; *accord Asacol*, 907 F.3d at 58, 61. Because Plaintiffs have done nothing to solve this dilemma, the same result should follow here.

III. PLAINTIFFS' PROPOSED INJUNCTION CLASS IS NOT CERTIFIABLE.

In its October 30 opinion denying Plaintiffs' request to certify an injunction class, the Court highlighted "the claim preclusive difficulties associated with injunction-only classes."

Op. at 53 (quoting *In re Skelaxin*, 299 F.R.D. at 555). The Court asked the parties to more fully discuss "the legal requirements of Rule 23(b)(2)" to determine whether certification of a nationwide injunctive relief class would be appropriate on the facts of this case. *Id.*

Plaintiffs have not carried their burden of showing that the injunction class satisfies the requirements of Rule 23(b)(2). At the most basic level, the Court cannot certify an injunctive relief class because Plaintiffs have not sufficiently articulated what specific injunctive relief they seek, whether it would be feasible, and how it could benefit members of the putative class where numerous other generic companies have filed ANDAs and either have litigated (and settled for entry dates as early as August 2019) or are currently litigating the validity of Celgene's numerous patents relating to Thalomid and Revlimid. The limited references to injunctive relief in Plaintiffs' motion come nowhere close to providing the Court with sufficient information to issue a (b)(2) certification order that satisfies Rule 65(d). This defect also undermines Plaintiffs' ability to prove that the class is sufficiently cohesive for class-wide injunctive relief because they cannot show how any injunction actually would impact any putative class member, much less the class as a whole. For all of these reasons, even if the Court were to conclude that the preclusive effects could be addressed, the Rule 23(b)(2) class should not be certified.

A. Plaintiffs' Failure to Specifically Define the Injunctive Relief Sought Precludes Certification.

Federal Rule of Civil Procedure 65(d) provides that "[e]very order granting an injunction . . . must: . . . state its terms specifically; and . . . describe in reasonable detail . . . the act or acts restrained or required." At the class certification stage, the requested injunctive relief "must be described in reasonably particular detail such that the court can at least conceive of an injunction that would satisfy Rule 65(d)'s requirements." *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 124, 169-70 (E.D. Pa. 2015) (quoting *Shook v. Bd. of Cty. Comm'rs of Cty. of El*

Paso, 543 F.3d 597, 605 (10th Cir. 2008)). "Moreover, Plaintiffs' sought injunction must be more specific than merely requiring that Defendants follow the law." *Processed Egg*, 312 F.R.D. at 170.

Plaintiffs have not proffered any proposed permanent injunction order in connection with their original or renewed motion, nor have they explained exactly what an injunction would include or why it would be necessary to redress the anticompetitive effects alleged in this case (delayed generic entry). They make passing reference to "restor[ing] the market to the natural competitive equilibrium that would exist but for Celgene's ongoing anticompetitive conduct," Mot. at 26, and assert that "[e]ach class member would benefit from an order requiring Celgene to delist its REMS patents from the Orange Book, or requiring it to supply samples within one month of request, for example," *id*. at 27. But as the Third Circuit has explained, the provision of an incomplete list of examples cannot substitute for the required comprehensive description. *See Wachtel ex rel. Jesse v. Guardian Life Ins. Co. of Am.*, 453 F.3d 179, 189 (3d Cir. 2006) (vacating class certification where "[t]he very use of the phrase '*inter alia*' ('among other things') in the [certification order] suggests that it is intentionally incomplete"); *Processed Egg*, 312 F.R.D. at 170 (stating that plaintiffs' use of the phrase "inter alia" is an "acknowledge[ment] that they are 'not specifying the exact nature of the injunctive relief they seek'"). Plaintiffs' undefined injunctive relief thus fails the requirements of Rule 23.

Plaintiffs' two "examples" serve only to highlight the inappropriateness of a class-wide injunction in this case. Plaintiffs' suggestion that Celgene be ordered to sell samples of its products to generic companies "within one month of request," Mot. at 27, is indefensible for several reasons. For starters, Plaintiffs allege no *current* anticompetitive conduct with respect to any of the generic companies that Plaintiffs allege were improperly denied samples. *Cf.*

Processed Egg, 312 F.R.D. at 169 ("[B]efore the Court can determine whether an injunction could be based on grounds that have general application to the class, it must know what policies of Defendants are *ongoing and threaten future injury*, and how any injunction could provide relief." (emphasis added)). In other words, Plaintiffs do not identify any generic company to whom they would have Celgene be ordered to sell samples today. For all of the generic companies referenced in Plaintiffs' complaint, Celgene has either already provided the requested samples, the generic company has abandoned the request, or the issue is being separately litigated. *See* Appendix A (attached herewith). So what exactly would the injunction require Celgene to do?

Any such injunction would, moreover, have no meaningful effect in the marketplace: numerous generic companies have already filed ANDAs with the FDA to market generic versions of these drugs. *Id*. And, for each of those, Celgene is either currently engaged in patent litigation against the generic company or has already reached settlements that provide for entry of these drugs at fixed future dates. *Id*. Pursuant to those settlements, a generic Thalomid product may be available as soon as August 2019, with a generic Revlimid product potentially available in 2022. *Id.*

Finally, to the extent Celgene receives a new sample request in the future, Plaintiffs' arbitrary 30-day timeline would require the Court to conclude that *any* refusal to sell to a competitor is *per se* unreasonable as there are myriad legitimate reasons why Celgene may not proceed with a sale. For example, under such an injunction, Celgene may be forced to sell samples to a generic company that had failed to obtain FDA approval—a conclusion that Judge Salas recently rejected. *See Mylan Pharm. v. Celgene Corp.*, No. 14-2094, Dkt. 287, at 13-28 (D.N.J. Oct. 3, 2018) (holding that, as a matter of law, it was objectively reasonable for Celgene

to require FDA approval prior to any sale).

Plaintiffs' suggestion that the Court should force Celgene to "delist its REMS patents from the Orange Book" is equally flawed. Mot. at 27. Every patent litigation Celgene is in with a company seeking to make a generic version of Thalomid or Revlimid contains patents-in-suit other than the REMS patents. *See* Appendix A. In other words, even if Celgene delisted its REMS patents, generic entry would not be accelerated because patent litigation would still occur regarding several other patents. In addition, Plaintiffs nowhere explain why they would be entitled to an injunction requiring Celgene to delist all of its REMS patents where (1) its sham litigation claims involve only a small subset of those patents, and (2) the validity of those patents already is being litigated both in this Court and before the Patent Trial and Appeal Board. In any event, Plaintiffs offer no explanation for why these examples of injunctive relief would be necessary or appropriate to address any alleged delayed generic entry or feasible given the allegations in this case.

B. Plaintiffs Cannot Demonstrate that the Class Is Cohesive.

Plaintiffs' failure to articulate the specific injunctive relief they seek also dooms Plaintiffs' attempt to show that the class is cohesive. A class action is maintainable under Rule 23(b)(2) only when "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class *as a whole*." Fed. R. Civ. P. 23(b)(2) (emphasis added). As the *Processed Egg* Court explained: "[G]iven the lack of clarity regarding what present violations of the antitrust laws require what types of injunctive relief," the class cannot be certified because "[t]he Court has not been presented with evidence as to how such relief would provide appropriate final relief to the class as a whole." *Processed Egg*, 312 F.R.D. at 169. So too, here.

Plaintiffs cannot demonstrate cohesiveness for the additional reason that they cannot

show class-wide injury through common proof. A (b)(2) class is cohesive if "'[its] claims are common ones and . . . adjudication of the case will not devolve into consideration of myriad individual issues.'" *Processed Egg*, 312 F.R.D. at 169 (quoting Newberg on Class Actions § 4:34). "In other words, Rule 23(b)(2) applies *only* when a single injunction or declaratory judgment would provide relief to *each* member of the class." *Id.* (emphasis added) (internal quotation marks omitted). Therefore, as Plaintiffs acknowledge, to demonstrate cohesiveness, they "must show that the following elements are susceptible of common proof: (1) actual or threatened injury . . . (2) causation; and (3) likelihood that the equitable relief will redress the injury." Mot. at 26 (internal quotation marks and citation omitted). Indeed, because (b)(2) class members are bound by the action without the opportunity to opt out, "a (b)(2) class may require *more* cohesiveness than a (b)(3) class." *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 264 (3d Cir. 2011) (emphasis added) (internal quotation marks omitted). And where, as here, a class cannot be certified under (b)(3) because individual issues predominate, that class will often also fail to satisfy (b)(2). *See, e.g.*, *Kotsur v. Goodman Glob., Inc.*, 2016 WL 4430609, *9 n.10 (E.D. Pa. 2016); *Fosmire v. Progressive Max Ins. Co.*, 277 F.R.D. 625, 636 (W.D. Wash. 2011).

The injury Plaintiffs seek to redress through their (b)(2) class is the alleged "supracompetitive prices" putative class members paid for Thalomid and Revlimid due to delayed generic entry. Mot. at 26-27. For all the reasons discussed with respect to their damages classes, Plaintiffs cannot provide the requisite "common proof" that each class member suffered such an injury. *See supra* Part II.A-B (describing Plaintiffs' failure to provide common method for identifying uninjured brand loyalists and flat copay consumers). This failure precludes a finding of cohesiveness and provides another reason to deny Plaintiffs' (b)(2) class. *See, e.g.*, *In re Pharmacy Benefit Managers Antitrust Litig.*, 2017 WL 275398, at *28 (E.D. Pa. Jan. 18,

2017) (proposed (b)(2) class not sufficiently cohesive where plaintiffs lacked common evidence that all members suffered injury from anticompetitive effects of alleged conspiracy); *Skelaxin*, 299 F.R.D. at 578 (denying (b)(2) certification where "the Court is unable to determine without individualized inquiry which entities are members of the class").

C. Plaintiffs' Injunctive Relief Class Is Not Necessary to Obtaining the Relief They Seek.

As the Court noted, one prominent concern with certifying any (b)(2) class is the preclusive effect it may have on class members because they do not have the option to opt out of the class and may therefore be barred from bringing a subsequent suit for damages. Op. at 53; *see also Processed Egg*, 312 F.R.D. at 167-68 (discussing the "difficulties in certifying a Rule 23(b)(2) class alongside a Rule 23(b)(3) class," including specifically the "perils of claim preclusion"). To alleviate this concern—and any other unintended negative effects of class treatment—the Third Circuit has advised that courts may consider whether class-wide treatment is necessary to obtain injunctive relief. *Gayle v. Warden Monmouth Cty. Corr. Inst.*, 838 F.3d 297, 310 (3d Cir. 2016). That is, "there may be circumstances where class certification is not appropriate because in view of the declaratory or injunctive relief ordered on an individual basis, there would be no meaningful additional benefit to prospective class members in ordering classwide relief." *Id.*; *see also Gonzalez v. Corning*, 885 F.3d 186, 194 n.3 (3d Cir. 2018) (applying *Gayle* in affirming denial of certification when class-wide injunction not necessary); *Processed Egg*, 312 F.R.D. at 170 (questioning whether "a nationwide class . . . as opposed to an individual action, is the appropriate form for this litigation"). This is just such a case.

In a typical (b)(2) class—such as "civil rights actions and other institutional reform cases"—a class-wide injunction is necessary to ensure class-wide relief. *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 142 (3d Cir. 1998) (internal quotation marks omitted). For example, if a

defendant illegally discriminates against an entire class of people, an injunction with respect to one plaintiff would not stop the behavior with respect to every other putative class member. That rationale does not apply here. Plaintiffs concede that whatever injunctive relief they are seeking would benefit all injured putative class members. In other words, Plaintiffs need only vindicate their own individual injunction claims to obtain any requested relief; there is thus no added benefit to class-wide treatment. *See, e.g.*, *Hall v. Burger King Corp.*, 1992 WL 372354, at *11-12 (S.D. Fla. Oct. 26, 1992) (certification of (b)(2) class unnecessary in suit alleging antitrust conspiracy because "the relief ordered in connection with an individual's claim or action . . . would of necessity inure to the benefit of others" (internal quotation marks omitted)).

Celgene does not believe Plaintiffs will be able to establish the bases for any injunction in this case, whether individually or as a class. But even if they could, such relief would not, as a practical matter, impact only the named Plaintiffs. Denying certification of an injunctive relief class, and allowing the named Plaintiffs to try to establish the grounds for a permanent injunction at a later time, is vastly preferable to the inadequate suggestions Plaintiffs offer for avoiding unintended preclusive effects. Plaintiffs' first recommendation is that this Court expressly reserve class members' right to seek monetary relief in a subsequent action. Mot. at 29. But, as several courts have noted, such a reservation may not be honored by subsequent courts. *See In re Vitamin C Antitrust Litig.*, 279 F.R.D. 90, 116 (E.D.N.Y. 2012); *Processed Egg*, 312 F.R.D. at 167; *Skelaxin*, 299 F.R.D. at 578. And Plaintiffs' second recommendation—that the Court limit the injunction class to just entities and/or persons in the nineteen states without *Illinois Brick* repealer statutes—essentially acknowledges that reducing the class size does not affect the relief all end payors would obtain from any injunction. Plaintiffs further concede that they do not presently have a named plaintiff who could assert claims under these laws. Mot. at 30 n.42.

Therefore, to avoid any preclusive effect as to those (or any other) class members—and in light of Plaintiffs' failure to identify the specific injunctive relief sought and prove the class is cohesive—the better course of action is to deny certification of an injunctive relief class.

CONCLUSION

Plaintiffs' Motion for Class Certification should be denied in its entirety.

Respectfully submitted,

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Dated: January 25, 2019